IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

LINDA WINFREE, as Next-of-Kin for MICHAEL SHOWERS, Decedent, Plaintiff, v. COOK GROUP, INCORPORATED, COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK MEDICAL, LLC, and COOK INCORPORATED, Defendants.	Civil Action No. COMPLAINT AND JURY DEMAND

COMPLAINT

COMES NOW Plaintiff, who by and through the undersigned counsel hereby submits this Complaint and Jury Demand against COOK GROUP, INC., COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK MEDICAL, LLC, and COOK INCORPORATED, hereinafter collectively referred to as "Cook" and/or "Defendants" for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from Decedent Michael Shower's injuries from his inferior vena cava ("IVC") filter manufactured by Defendants. In support of this Complaint, Plaintiff alleges the following:

INTRODUCTION

1. This is an action for damages against COOK GROUP, INC., COOK MEDICAL INCORPORATED a/k/a COOK MEDICAL, INC., COOK MEDICAL, LLC, and COOK INCORPORATED, hereinafter collectively referred to as "Cook" and/or "Defendants."

2. The allegations, claims and theories of recovery relate to the Defendants' design, manufacture, sale, testing, marketing, labeling, advertising, promotion and/or distribution of their unsafe medical devices known as Gunther Tulip Mreye, Gunther Tulip Vena Cava Filter, Cook

Celect Vena Cava Filter, and Cook Celect Platinum, hereinafter "Cook IVC Filters" or "Cook's IVC Filters."

3. Cook IVC Filters are associated with, and cause, an increased risk for serious injury and death as a result of adverse events including tilting, perforation, fracture, breakage and migration.

4. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently failed to act as to the known failures and injuries associated with their devices and/or failed to warn about and concealed, suppressed, omitted, and/or misrepresented the risks, dangers, defects and disadvantages of its IVC Filters.

5. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently advertised, labeled, promoted, marketed, sold and/or distributed its IVC Filters as a safe medical device when in fact Cook had reason to know, and/or did know, that its IVC Filters were not safe for their intended purposes, and that its IVC Filters caused serious injury and death.

6. At all times relevant to this action, Cook is and was strictly liable for injuries caused by its IVC Filters because the devices are unreasonably dangerous and not accompanied by adequate warnings about its danger.

7. As a direct and proximate result of having Defendants' Gunther Tulip IVC Filter implanted in him, Decedent suffered permanent and continuous injuries, pain and suffering, disability and impairment. Decedent suffered emotional trauma, harm and injuries. Plaintiff lost his ability to live a normal life. Furthermore, Plaintiff lost earnings and had medical bills related to care because of the Gunther Tulip IVC filter's defects.

PARTIES

Plaintiff

8. Plaintiff Linda Winfree ("Ms. Winfree" or "Plaintiff") is a citizen and resident of Front Royal, Warren County, Virginia.

9. Ms. Winfree is Next-of-Kin for natural brother, Decedent Michael Showers ("Mr. Showers" or "Decedent").

10. Mr. Showers was implanted with a Cook Gunther Tulip IVC Filter by Dr. Gary Thomas Marshall, M.D., at Vanderbilt University Medical Center in Nashville, Tennessee on August 18, 2006.

11. On September 29, 2021, a review of Mr. Showers' CT scan revealed "[a]ll the struts of the IVC filter perforate the IVC up to 14mm. One (1) anterior strut perforates the IVC wall 4mm and resides within the soft tissues. One (1) medial strut perforates the IVC wall 9mm and contacts the aorta. One (1) posterior strut perforates the IVC wall 10mm and resides within the soft tissues. One (1) medial strut perforates the IVC wall 14 mm and contacts a right lumber artery."

12. Mr. Showers suffered anxiety, fear, depression, and pain as a result of his injuries caused by the Gunther Tulip IVC Filter implanted in him.

13. Mr. Showers died on April 11, 2018 from causes unrelated to the implant of the Gunther Tulip IVC filter.

Defendants

14. Defendant Cook Group, Incorporated is an Indiana Corporation with a principal place of business located at 750 Daniels Way, Bloomington, Indiana 47404. Defendant Cook Group, Incorporated regularly conducts business in the State of Tennessee, and is authorized to do so. Defendant Cook Group, Incorporated may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

15. Defendant Cook Group, Incorporated is the parent company of Defendant Cook Medical, Incorporated and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana 47402. Defendant Cook Group, Incorporated regularly conducts business in the State of Tennessee, and is authorized to do so.

Defendant Cook Medical, Incorporated may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

16. Defendant Cook Group, Inc. is the parent company of Defendant Cook Medical LLC and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Incorporated regularly conducts business in the State of Tennessee, and is authorized to do so. Defendant Cook Medical, LLC may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

17. Defendant Cook Group, Inc. is the parent company of Defendant Cook Incorporated and is an Indiana Corporation with a principal place of business located at 750 Daniels Way, P.O. Box 1608, Bloomington, Indiana 47402. Defendant Cook Group Incorporated regularly conducts business in the State of Tennessee, and is authorized to do so. Defendant Cook Incorporated may be served with process upon its registered agent for service: C/O CSC Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

18. At all times alleged herein, the Cook defendants include any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

19. Cook develops, manufactures, sells and distributes medical devices for use in various medical applications including endovascular cardiology and surgical products throughout the United States and around the world. Cook's product at issue in this matter is the Gunther Tulip Vena Cava Filter which is used for the prevention of recurrent pulmonary embolism via placement in the vena cava.

JURISDICTION AND VENUE

20. Federal subject matter jurisdiction is based upon 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs.

21. Defendants have significant contacts with this federal judicial district therefore they are subject to the personal jurisdiction of the Court in this district. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in this federal judicial district and therefore, pursuant to 28 U.S.C. § 1391(b), venue is proper in this district.

FACTUAL BACKGROUND

22. Defendants design, research, develop, manufacturer, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. Defendants' products include the Cook Celect Vena Cava Filter and the Gunther Tulip Filter (collectively referred to herein as "Cook Filters"), which are introduced via a coaxial introducer sheath system. Defendants sought Food and Drug Administration ("FDA") approval to market the Cook Filters and/or their components under Section 510(k) of the Medical Device Amendment.

23. Section 510(k) allows marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., 376 F.3d 163, 167 (3d Cir. 2004):

> A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with section 510(k)…A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective. (Emphasis in original).

24. In *Medtronic, Inc. v. Loehr*, 518 U.S. 470,478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis…The §510(k) notification process is by no means comparable to the [premarket approval] process; in contrast to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in an average of 20 hours…Section §510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed quickly.

25. An IVC filter, like the Cook Filters, is a device designed to filter blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

26. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs they are considered "pulmonary emboli" or PE. An IVC filter, like the Cook IVC Filters, is designed to prevent thromboembolic events.

27. The Cook Filters are retrievable filters.

28. The Cook Celect® Vena Cava Filter has four (4) anchoring struts for fixation and eight (8) independent secondary struts to improve self-centering and clot trapping.

29. The Gunther Tulip® Vena Cava Filter has a top hook and (4) anchoring struts for fixation and on each strut, it has a "flower" formation that is shorter than the strut where a wire piece branches out on each side of the strut forming an overall "flower" type formation on each strut.

30. At all times relevant hereto, the Cook Filters were widely advertised and promoted by the Defendants as safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava. At all times relevant hereto, Defendants knew their Cook Filters

were defective and knew that defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

31. A retrospective review of all Cook Gunther Tulip Filters and Cook Celect filters retrieved between July 2006 and February 2008 was performed. One hundred and thirty (130) filter retrievals were attempted but in 33 cases, the standard retrieval technique failed. The authors concluded that "unsuccessful retrieval was due to significant endothelialization and caval penetration" and that "hook endothelialization is the main factor resulting in failed retrieval and continues to be a limitation with these filters." O. Doody, et al.; "Assessment of Snared-Loop Technique When Standard Retrieval of Inferior Vena Cava Filters Fail" Cardiovasc Intervent Radiol (Sept. 4, 2008 Technical Note).

32. A retrospective review of 115 patients who underwent Cook Celect IVC filter insertion between December 2005 and October 2007 was performed. While filter insertion was successful in all patients, the authors also concluded that "[f]ailed retrieval secondary to hook endothelialization continues to be an issue with this filter." O. Doody, et al; Journal of Medical Imaging and Radiation Oncology "Initial Experience in 115 patients with the retrievable Cook Celect vena cava filter" 53 (2009) 64-68 (original article).

33. In a review of clinical data related to 73 patients who had Celect IVC filters implanted between August 2007 and June 2008, the authors found that the Celect IVC filter was related to a high incidence of caval filter leg penetration. Immediately after fluoroscopy-guided filter deployment in 61 patients, four filters (6.5%) showed significant tilt. Follow-up abdominal CT in 18 patients demonstrated filter related problems in 7 (39%), which included penetration of filter legs in 4 and fracture/migration of filter components in 1.

34. In a study of Gunther Tulip and Celect IVC filters implanted between July 2007 and May of 2009 reported by Cardiovascular Interventional Radiology electronically on March 30, 2011

and published by journal in April 2012, one hundred percent of the Cook Celect filters and Gunther Tulip filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall. Durack JC, et al, Cardiovasc Intervent Radiol., "Perforation of the IVC: rule rather than the exception after longer indwelling times for the Gunther Tulip and Celect Retrievable Filters," 2012 Apr.; 35(2):299-308. Epic 2011 Mar 30. The authors concluded: "Although infrequently reported in the clinical literature, clinical sequelae from IVC filter components breaching the vena cava can be significant." Defendants knew or should have known that their IVC filters were more likely than not to perforate the vena cava wall.

35. This same study reported that tilt was seen in 20 out of 50 (40%) of the implanted Gunther Tulip and Celect IVC filters and all tilted filters also demonstrated vena caval perforation. Defendants knew or should have known that their IVC filters were more likely than not tilt and to perforate.

36. While not inclusive of all medical studies published during the relevant time period, the above references show that the Defendants failed to disclose to physicians, patients and/or Decedent that their Cook Filters were subject to breakage, tilt, inability of removal, and migration even though they knew or should have known the same was true**.**

37. At all times relevant hereto, the Defendants continued to promote the Cook Filter as safe and effective even when inadequate clinical trials had been performed to support safety and/or efficacy.

38. The Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Cook Filters, as aforesaid.

39. The Cook Filters are constructed of conichrome.

40. The Defendants specifically advertise the conichrome construction of the filter as a frame which "reduces the risk of fracture."

41. The failure of the Cook Filters is attributable, in part, to the fact that the Cook Filters suffer from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

42. At all times relevant hereto, the Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Cook Filters, including, but not limited to, the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo.*

43. The Cook Filters were designed, manufactured, distributed, sold and/or supplied by the Defendants, and were marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Defendants' knowledge of the products' failure and serious adverse events.

44. That at all times relevant hereto, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of the said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Decedent.

FRAUDULENT CONCEALMENT, DISCOVERY RULE, EQUITABLE ESTOPPEL AND WAIVER, AND TOLLING OF THE STATUTE OF LIMITATIONS

45. Defendants are equitably estopped from claiming that Plaintiff's claims are barred by the statute of limitations in the present action.

46. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Decedent and Decedent's healthcare providers the true and significant risks associated with Cook's Gunther Tulip IVC Filter, including but not limited to tilting, perforation, fracture, breakage and migration.

47. Cook Defendants' sales representative who sold Cook's Gunther Tulip IVC Filter to Decedent's implanting physician concealed the above-referenced risks shortly before and/or during Decedent's implantation procedure.

48. Cook Defendants' sales representative who sold Cook's Gunther Tulip IVC Filter to Decedent's implanting physician concealed the above-referenced risks at all times relevant after Decedent's implantation procedure through the present.

49. Prior to Decedent's implantation procedure, his implanting physicians attended an event(s) where they were trained on how to implant Cook's Gunther Tulip Filter into their patients, including Decedent. During these training session(s) or event(s), Defendants made affirmative representations and/or concealments of the above-referenced risks they knew about.

50. Decedent's implanting physician(s) reasonably relied on Defendants' affirmative representations and/or concealments of the above-referenced risks because they recommended implantation of their Gunther Tulip IVC Filter to Decedent.

51. As a result of Defendants' actions, Decedent and his prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Decedent had been exposed to the risks identified in this Complaint, and that those risks were the result of Defendants' acts, omissions, and misrepresentations.

52. Accordingly, no limitations period ought to accrue until such time as Decedent knew or reasonably should have known of some causal connection between Decedent being implanted with a Cook IVC Filter and the harm Decedent suffered as a result.

53. Additionally, the accrual and running of any applicable statute of limitations have been tolled by reason of Defendants' fraudulent concealment.

54. Additionally, Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described.

55. Additionally, the limitations period ought to be tolled under principles of equitable estoppel or tolling.

CAUSES OF ACTION

COUNT I
TENNESSEE PRODUCT LIABILITY ACT

A. GENERAL NEGLIGENCE AND FAILURE TO WARN OR INSTRUCT

56. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

57. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, manufacturing, marketing and selling sophisticated medical devices, including their Cook Gunther Tulip IVC Filter.

58. At all times relevant hereto, the Cook Defendants were under a duty to act reasonably to design, develop, manufacture, market and sell a product that did not present a risk of harm or injury to the Decedent and to those people receiving their Gunther Tulip IVC Filter.

59. At the time of manufacture and sale of the Cook Gunther Tulip IVC Filters, the Cook Defendants knew or reasonably should have known the Cook Gunther Tulip IVC Filter:

a. was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;

c. was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

d. was designed and manufactured so as to present an unreasonable risk of perforation and damage to the vena cava wall.

60. Despite the aforementioned duty on the part of the Cook Defendants, they committed

one or more breaches of their duty of reasonable care and were negligent in:

a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Cook Gunther Tulip IVC Filter, specifically their incidents of fracture, migration, perforation and other failure;

b. unreasonably and carelessly manufactured a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

c. unreasonably and carelessly designed a product that presented a risk of harm to the Decedent and others similarly situated in that it was prone to fail.

61. As a direct and proximate result of the Cook Gunther Tulip IVC Filter's defects, as described herein, Decedent suffered permanent and continuous injuries, pain and suffering, disability and impairment. Decedent suffered emotional trauma, harm and injuries. Decedent lost his ability to live a normal life. Furthermore, Decedent lost earnings and had medical bills related to care because of the Cook Gunther Tulip IVC Filter's defects.

62. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Decedent and healthcare professionals about the increased risk of serious injury and death caused by their defective Gunther Tulip IVC filter.

63. WHEREFORE**,** Plaintiff demands judgment against the Cook Defendants and seeks damages including: compensatory damages, punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

B. NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

64. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed, and sold Defendants' Gunther Tulip IVC filter to Decedent, carelessly and negligently concealed the harmful effects of the Defendants' Gunther Tulip IVC filter from Decedent, and carelessly and negligently misrepresented the quality, safety, and efficacy of the Gunther Tulip IVC filter.

65. Defendants maintained a duty to Decedent and his implanting physician to inform them of the defective propensities and harmful effects of their Gunther Tulip IVC filter.

66. Defendants maintained a duty to Decedent and his implanting physician to accurately represent the qualities and efficacy of their Gunther Tulip IVC filter.

67. Defendants breached their above-referenced duties owed to Decedent and his implanting physician, as further detailed in this Complaint.

68. Decedent was clearly within the zone of danger of physical impact of the Gunther Tulip IVC filter considering it was still implanted in him at the time of his death.

69. Decedent reasonably feared for his own safety due to the Gunther Tulip IVC Filter implanted in him. Decedent suffered constant threats to his own personal security as long as Defendants' Gunther Tulip IVC Filter remained implanted in him.

70. Decedent was directly impacted by Defendants' carelessness and negligence, in that Decedent sustained emotional distress, severe physical injuries, economic losses, and other damages as a direct result of being implanted with the Gunther Tulip IVC filter sold and distributed by Defendants.

71. Decedent sustained physical injuries, including but not limited to pain and suffering, that were caused by psychological trauma (stress, anxiety, sadness, anger, etc.) related to the Defendants' above-referenced conduct.

72. Decedent's above-referenced emotional distress was and is so severe that no reasonable person could have been expected to endure it. Decedent's emotional distress was medically diagnosable.

73. Defendants' above-referenced conduct is so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized community.

74. Decedent was under constant fear that the Gunther Tulip IVC Filter could tilt, fracture, break, migrate and/or perforate his vein or other bodily organs.

75. Decedent knew that the Gunther Tulip IVC Filter in his body could tilt, fracture, break, migrate and/or perforate his vein or other bodily organs; he was very stressed and anxious since the Gunther Tulip IVC Filter was behaving this way.

76. As a direct and proximate result of the Cook Gunther Tulip IVC Filter's defects, as described herein, Decedent suffered permanent and continuous injuries, pain and suffering, disability and impairment. Decedent suffered emotional trauma, harm and injuries. Decedent lost his ability to live a normal life. Furthermore, Decedent lost earnings and had medical bills related to care because of the Cook Gunther Tulip IVC Filter's defects.

C. GROSS NEGLIGENCE

77. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

78. Defendants' conduct was willful and wanton, showing an utter indifference to or conscious regard for the safety of others, the public, and Decedent for which the law would allow, and which Plaintiff will seek the imposition of punitive or exemplary damages, in that Defendants' conduct, when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded

with conscious indifference to the rights, safety, or welfare of others.

79. The acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Decedent. In that regard, Plaintiff will seek punitive or exemplary damages in an amount that would punish Defendants for their conduct, and which would deter other manufacturers from engaging in such misconduct in the future.

80. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, and such further relief as the Court deems equitable and just.

COUNT II
NEGLIGENCE PER SE
(Violation of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807, 820)

81. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

82. At all times herein mentioned, Defendants had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning and post-sale warning and other communications of the risks and dangers of Cook Gunther Tulip IVC Filter.

83. By reason of their conduct as alleged herein, Defendants violated provisions of statutes and regulations, including but not limited to, the following:

a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§331 and 352, by misbranding its Cook Gunther Tulip IVC Filter;

b. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 in making statements and/or representations via word, design, device or any combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Cook Gunther Tulip IVC Filter to which the labeling and advertising relates;

c. Defendants violated 21 C.F.R. §1.21 in misleading the consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of their Cook Gunther Tulip IVC Filter;

d. Defendants violated 21 C.F.R. §801 in mislabeling their Cook Gunther Tulip IVC Filter as to the safety and effectiveness of their products and by failing to update their label to reflect post-marketing evidence that their Cook Gunther Tulip IVC Filter was associated with an increased risk of injuries due to tilting, fracture, migration and perforation;

e. Defendants violated 21 C.F.R. §803 by not maintaining accurate medical device reports regarding adverse events of tilting, fracture, migration and perforation and/or misreporting these adverse events maintained via the medical device reporting system;

f. Defendants violated 21 C.F.R. §807 by failing to notify the FDA and/or the consuming public when their Cook Gunther Tulip IVC Filter was no longer substantially equivalent with regard to safety and efficacy with regard to post-marketing adverse events and safety signals; and

g. Defendants violated the 21 C.F.R. §820 by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions.

84. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages including: compensatory damages, punitive damages, together with interest, the costs of

suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT III
TENNESSEE PRODUCT LIABILITY ACT

A. STRICT LIABILITY-DESIGN DEFECT

85. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

86. Plaintiff brings a design defect claim based on strict products liability theory.

87. The Gunther Tulip IVC Filter as designed posed a substantial likelihood of harm.

88. The reasons that Defendants' Gunther Tulip IVC Filter as designed posed a substantial likelihood of harm include, but are not limited to:

a. was designed in such a manner so as to present an unreasonable risk of fracture of portions of the device, as aforesaid;

b. was designed so as to present an unreasonable risk of migration of the device and/or portions of the device;

c. was designed to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

d. was designed so as to present an unreasonable risk of perforation and damage to the vena cava wall.

89. It was feasible to design the product in a safer manner because Defendants:

a. designed a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body; and

b. designed a product that presented a risk of harm to the Decedent and others similarly situated in that it was prone to fail.

90. As a direct and proximate result of the Cook Gunther Tulip IVC Filter's design defects, as described herein, the defective design was a substantial factor in causing Decedent's

injuries.

91. As a direct and proximate result of the Cook Gunther Tulip IVC Filter's defects, as described herein, Decedent suffered permanent and continuous injuries, pain and suffering, disability and impairment. Decedent suffered emotional trauma, harm and injuries. Decedent lost his ability to live a normal life. Furthermore, Decedent lost earnings and had medical bills related to care because of the Cook Gunther Tulip IVC Filter's defects.

92. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their design of their Gunther Tulip IVC Filter resulting in the product to be unreasonably dangerous and defective.

B. STRICT LIABILITY - FAILURE TO WARN

93. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

94. Plaintiff brings a failure to warn claim based on strict product liability theory.

95. Defendants had a duty to individuals, including the Decedent and his implanting physician, to warn of latent dangers resulting from intended or reasonably foreseeable unintended uses of the Gunther Tulip IVC filter and use reasonable care in providing adequate warnings for their Gunther Tulip IVC Filter.

96. Defendants failed to warn or instruct the Decedent and/or his implanting physician of known subjects including, but not limited to, the following:

a. Cook Gunther Tulip IVC Filters contained warnings insufficient to alert consumers, including Decedent, of the dangerous risks associated with the subject product, including but not limited to the risk of tilting, perforation, fracture and migration which are associated with and did cause serious injury;

b. information provided by Defendants to the medical community and to

consumers concerning the safety and efficacy of their Gunther Tulip IVC Filter did not accurately reflect the serious and potentially fatal adverse events Decedent could suffer;

c. at all times relevant hereto, the Cook Gunther Tulip IVC Filter was dangerous and presented a substantial danger to patients who were implanted with the Cook Gunther Tulip IVC Filter, and these risks and dangers were known or knowable at the times of distribution and implantation in Decedent. Ordinary consumers would not have recognized the potential risks and dangers the Cook Gunther Tulip IVC Filter posed to patients, because their use was specifically promoted to improve health of such patients, including Decedent;

d. had adequate warnings and instructions been provided, Decedent would not have been implanted with Cook Gunther Tulip IVC Filter, and would not have been at risk of the harmful injuries described herein. The Defendants failed to provide warnings of such risks and dangers to the Decedent and his medical providers as described herein. Neither Decedent, nor Decedent's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cooks' Gunther Tulip IVC Filter;

e. Defendants knew or had knowledge that the warnings that were given failed to properly warn of the increased risks of serious injury associated with and/or caused by Cook Gunther Tulip IVC Filter;

f. Decedent, individually and through his implanting physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants; and

g. Defendants had a continuing duty to warn Decedent and his implanting physicians of the dangers associated with the subject product.

97. Defendants' IFU for the Gunther Tulip IVC Filter product is defective, deficient, and/or insufficient because it does not warn of every single injury experienced by Decedent and the

causes of those injuries.

98. Defendants' IFU for the Gunther Tulip product is defective, deficient, and/or insufficient because it does not list known adverse events and risks that caused the injuries that Decedent sustained.

99. Defendants' Cook Gunther Tulip IVC Filter product IFU is deficient because it fails to detail the extent and frequency of known complications, including migration, titling, fracture and perforation, experienced by Decedent.

100. At a minimum, if Defendants provided and conveyed to Decedent's implanting physician all known defective propensities, risks, adverse events, and contraindications of the Gunther Tulip product, this learned intermediary would have considered this information in the consent process with Decedent. No reasonable physician would knowingly implant a defective product or a product that would not work or a product that would exhibit the above-referenced defective propensities and cause associated injuries in their patients. The same can be said for Decedent's implanting physician. Ultimately, it was Decedent's decision as to whether or not he would consent to the Gunther Tulip product implanted in him, and he would have not consented to the Gunther Tulip being implanted in him.

101. If Defendants provided Decedent's implanting physician with adequate warnings in the Gunther Tulip IFU or other materials provided, Decedent's implanting physician would have heeded those warnings.

102. If Decedent's implanting physician was adequately warned by being informed of all known risks, adverse events, and contraindications of the Gunther Tulip product, Decedent's implanting physician would have warned Decedent of the same.

103. Decedent's implanting physician would have changed his consent process and/or not recommended or prescribed Defendants' Gunther Tulip product to Decedent if Defendants had given proper and adequate warnings to him.

104. If Decedent was properly consented to the Gunther Tulip product by being informed of all relevant risks, adverse events, and contraindications of the device – which he was not – he would not have consented to have the Gunther Tulip product implanted in him and the sequalae and injuries he experienced.

105. Decedent relied on his implanting physician to inform him about all material facts regarding the risks, adverse events, and contraindications of the Gunther Tulip.

106. Decedent used the the Gunther Tulip IVC Filter in a reasonably foreseeable manner.

107. As a direct and proximate result of the Cook Gunther Tulip IVC Filter's defects, as described herein, Decedent suffered permanent and continuous injuries, pain and suffering, disability and impairment. Decedent suffered emotional trauma, harm and injuries. Decedent lost his ability to live a normal life. Furthermore, Decedent lost earnings and had medical bills related to care because of the Cook Gunther Tulip IVC Filter's defects.

108. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their failure to warn and/or adequately warn the Decedent and his healthcare, implanting professionals about the increased risk of serious injury and death caused by their defective Gunther Tulip IVC Filter.

109. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages including: compensatory damages, punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT IV
BREACH OF EXPRESS WARRANTY

110. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

111. Decedent, though his medical providers, purchased a Cook Gunther Tulip IVC Filter from the Cook Defendants.

112. At all times relevant to this cause of action, the Cook Defendants were merchants of goods of the kind including medical devices and vena cava filters (i.e., Cook Gunther Tulip IVC Filters).

113. At the time and place of sale, distribution and supply of the Cook Gunther Tulip IVC Filter to Decedent (and to other consumers and the medical community), the Defendants expressly represented and warranted in their marketing materials, both written and orally, and in the Instructions for Use ("IFU"), that the Cook Gunther Tulip IVC Filter was safe, well-tolerated, efficacious, and fit for its intended purpose and was of marketable quality, that it did not produce any unwarned-of dangerous side effects, and that it was adequately tested.

114. At the time of Decedent's purchase from Defendants, the Cook Gunther Tulip IVC Filter was not in a merchantable condition and Defendants breached their expressed warranties, in that the filter:

a. was designed in such a manner so as to be prone to a unreasonably high incident of fracture, perforation of vessels and organs, and/or migration;

b. was designed in such a manner so as to result in a unreasonably high incident of injury to the organs of its purchaser; and

c. was manufactured in such a manner so that the exterior surface of the Cook Gunther Tulip Filter was inadequately, improperly and inappropriately designed causing the device to weaken and fail.

115. By and through commercial documents that may have been provided to Decedent, Defendants expressly warranted that the Gunther Tulip filter was safe and effective.

116. Defendants breached the above-referenced express warranties which are otherwise false.

117. Decedent was in privity with Defendants as the third-party, intended beneficiary of the Gunther Tulip product.

118. Decedent, by and through his implanting physician(s), relied on the above-referenced warranties in consenting to the implant procedure.

119. Defendants' warranties were made to benefit Decedent as a patient – not to benefit his implanting physician(s) or the hospital Defendants sold the Gunther Tulip to – such that Decedent was the intended consumer of the Gunther Tulip device.

120. Defendants breached these express warranties because the Gunther Tulip product implanted in the Decedent was unreasonably dangerous and defective, as described herein, and not as Defendants had represented. The above-referenced warranties were breached or are otherwise false, and they ran with the product.

121. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective Gunther Tulip product in Decedent, placing Decedent's health and safety in jeopardy.

122. As a direct and proximate result of the Cook Gunther Tulip IVC Filter's defects, as described herein, Decedent suffered permanent and continuous injuries, pain and suffering, disability and impairment. Decedent suffered emotional trauma, harm and injuries. Decedent lost his ability to live a normal life. Furthermore, Decedent lost earnings and had medical bills related to care because of the Cook Gunther Tulip IVC Filter's defects.

123. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their breach express warranty.

124. WHEREFORE**,** Plaintiff demands judgment against the Cook Defendants and seeks damages including compensatory damages, punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT V
TENNESSEE PRODUCT LIABILITY ACT - BREACH OF IMPLIED WARRANTY

125. Plaintiff incorporates by reference each and every material fact of this Complaint as

if fully set forth herein.

126. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold their Gunther Tulip IVC Filter.

127. At all relevant times, the Defendants intended their Gunther Tulip IVC Filter to be used in the manner that Decedent in fact used it.

128. Defendants impliedly warranted their Gunther Tulip IVC Filter to be of merchantable quality, safe and fit for the use for which the Defendants intended it and for which Decedent in fact used it.

129. Defendants breached their implied warranties as follows:

a. Defendants failed to provide the warning or instruction and/or an adequate warning or instruction which a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that their Cook Gunther Tulip IVC Filter would cause harm;

b. Defendants manufactured and/or sold their Cook Gunther Tulip IVC Filter and said filter did not conform to representations made by the Defendants that the device was safe and effective, provided a permanent solution to pulmonary embolism, would not migrate, fragment, tilt, and/or perforate when it left the Defendants' control;

c. Defendants manufactured and/or sold their Cook Gunther Tulip IVC Filter which was more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Cook Gunther Tulip Filter's design or formulation exceeded the benefits associated with that design. These defects existed at the time the products left the Defendants' control; and

d. Defendants manufactured and/or sold their Cook Gunther Tulip IVC Filter when they deviated in a material way from the design specifications, formulas or performance

standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards, and these defects existed at the time the product left the Defendants' control.

130. Further, Defendants' marketing of their Cook Gunther Tulip IVC Filter was false and/or misleading since the device is not safe and effective; does not provide a permanent solution to pulmonary embolism; and otherwise migrates, fragments, tilts, and/or perforates the IVC.

131. Decedent, through his attending physicians, relied on these representations in determining which IVC filter to use for implantation in him.

132. Defendants' Gunther Tulip filter was unfit and unsafe for use by users, including Decedent, as it posed an unreasonable and extreme risk of injury to Decedent, and accordingly Defendants breached their expressed warranties and the implied warranties associated with the product.

133. The foregoing warranty breaches were a substantial factor in causing Decedent's injuries and damages as alleged.

134. The Decedent, by and through his implanting physicians as his learned intermediaries, relied upon Defendants' implied warranties of merchantability in consenting to have the Gunther Tulip product implanted in him.

135. Decedent was the intended third-party beneficiary of Defendants' Gunther Tulip product since Defendants knew Decedent's implanting physicians intended to implant the Gunther Tulip IVC Filter in Decedent.

136. Privity of contract is inferred since Defendants' warranties of the Gunther Tulip IVC Filter ran with the product.

137. Defendants further breached their implied warranty that the Gunther Tulip that was implanted in Decedent is a permanent device and would not need to be retrieved.

138. As a direct and proximate result of the Cook Gunther Tulip IVC Filter's defects, as described herein, Decedent suffered permanent and continuous injuries, pain and suffering, disability and impairment. Decedent suffered emotional trauma, harm and injuries. Decedent lost his ability to live a normal life. Furthermore, Decedent lost earnings and had medical bills related to care because of the Cook Gunther Tulip IVC Filter's defects.

139. By reason of the foregoing, Defendants are liable to the Plaintiff for damages as a result of their breaches of implied warranty.

140. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks damages including compensatory damages, punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VI
NEGLIGENT MISREPRESENTATION

141. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

142. Defendants had a business and professional duty to accurately and truthfully represent to the medical and healthcare community, Decedent, the FDA, and the public, that the Gunther Tulip IVC Filter had not been found to be safe and effective.

143. Defendants maintained a business and professional duty to Decedent and his implanting physician to inform them of the defective propensities and harmful effects of their Gunther Tulip IVC Filter.

144. Defendants maintained a business and professional duty to Decedent and his implanting physician to accurately represent the qualities and efficacy of their Gunther Tulip IVC Filter.

145. The aforementioned misrepresentations were material.

146. Defendants knew or should have known that the aforementioned misrepresentations

were untrue.

147. At all times material, including immediately before and during the implantation consent process between Decedent and his implanting physician, Defendants breached their duty to inform Decedent's implanting physician, regulatory agencies (including the FDA), and the public of the risks, adverse events, and contraindications of the Gunther Tulip IVC Filter which came to, or should have come to, Defendants' attention.

148. Defendants failed to exercise ordinary care in their representations concerning the Gunther Tulip IVC Filter while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Gunther Tulip IVC Filter's high risk of unreasonable, dangerous, adverse side effects.

149. The facts misrepresented by Defendants to Decedent and his implanting physician were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use Defendants' Gunther Tulip IVC Filter.

150. Decedent and Decedent's implanting physician intended to rely and act upon the information provided by Defendants.

151. Decedent reasonably relied on Defendants' misrepresentations to his detriment.

152. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII
COMMON-LAW FRAUD

153. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

154. Defendants represented to the medical and healthcare community, Decedent, the FDA, and the public, that the Gunther Tulip IVC Filter was safe and effective.

155. The aforementioned representations were material.

156. The aforementioned representations were false.

157. When the Defendants made the representations, Defendants knew that they were false, or made them recklessly, without knowledge of their truth as positive assertions.

158. Defendants made the representations with the intention that the Decedent's implanting physician and Decedent would act upon them by proceeding with the implantation of the Gunther Tulip product.

159. Decedent's implanting physician and Decedent acted in reasonable reliance upon these representations by electing to have the Gunther Tulip IVC Filter implanted.

160. The false representations made by Defendants to Decedent and his implanting physician were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use Defendants' Gunther Tulip IVC Filter.

161. As a direct and proximate result of the Cook Gunther Tulip IVC Filter's defects, as described herein, Decedent suffered permanent and continuous injuries, pain and suffering, disability and impairment. Decedent suffered emotional trauma, harm and injuries. Decedent lost his ability to live a normal life. Furthermore, Decedent lost earnings and had medical bills related to care because of the Cook Gunther Tulip IVC Filter's defects.

162. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII
TENNESSEE PRODUCT LIABILITY ACT - FRAUDULENT CONCEALMENT

163. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

164. Defendants concealed or omitted material facts regarding the risks, adverse events, and contraindications from Decedent and his implanting physician. These material facts are detailed herein and include tilting, migration, fracture, breakage, and perforation.

165. The Defendants had a duty to disclose. Defendants had duty to accurately and truthfully represent to the medical and healthcare community, Decedent, the FDA, and the public, that the Gunther Tulip IVC Filter had not been adequately tested and found to be safe and effective.

166. Defendants had a duty to Decedent and his implanting physician to inform them of the defective propensities and harmful effects of their Gunther Tulip IVC Filter as detailed herein.

167. Defendants had a duty to Decedent and his implanting physician to accurately represent the qualities and efficacy of their Gunther Tulip IVC Filter.

168. Decedent's implanting physician and Decedent acted in reliance upon these concealed or omitted material fact by electing to have the Gunther Tulip IVC Filter implanted.

169. These omissions of material fact by Defendants were material because a reasonable person would have considered to be important in deciding whether or not to purchase and/or use Defendants' Gunther Tulip IVC Filter.

170. As a direct and proximate result of the Cook Gunther Tulip IVC Filter's defects, as described herein, Decedent suffered permanent and continuous injuries, pain and suffering, disability and impairment. Decedent suffered emotional trauma, harm and injuries. Decedent lost his ability to live a normal life. Furthermore, Decedent lost earnings and had medical bills related to care because of the Cook Gunther Tulip IVC Filter's defects.

171. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court

deems equitable and just.

COUNT IX
CONSTRUCTIVE FRAUD

191. Plaintiff incorporates by reference each and every material fact of this Complaint as if fully set forth herein.

192. Defendants represented to the medical and healthcare community, Decedent, the FDA, and the public, that the Gunther Tulip IVC Filter was safe and effective.

193. The aforementioned representations were material.

194. The aforementioned representations were false.

195. Defendants had a business and professional duty to accurately and truthfully represent to the medical and healthcare community, Decedent, the FDA, and the public, that the Gunther Tulip IVC Filter had not been found to be safe and effective.

196. Decedent's implanting physician and Decedent acted in reliance upon these representations by electing to have the Gunther Tulip IVC Filter implanted.

197. The false representations made by Defendants to Decedent and his implanting physician were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use Defendants' Gunther Tulip IVC Filter.

198. As a direct and proximate result of the Cook Gunther Tulip IVC Filter's defects, as described herein, Decedent suffered permanent and continuous injuries, pain and suffering, disability and impairment. Decedent suffered emotional trauma, harm and injuries. Decedent lost his ability to live a normal life. Furthermore, Decedent lost earnings and had medical bills both related to care because of the Cook Gunther Tulip IVC Filter's defects.

199. Defendants maintained a position of superiority over Decedent and his implanting physician such that fraud can be inferred even without the requisite intent.

200. As the intended, third party beneficiary of the Gunther Tulip, a quasi-fiduciary and/or

confidential relationship between Decedent and Cook Defendants existed.

201. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE**,** Plaintiff demands judgment against the Cook Defendants as follows:

A. compensatory damages to Plaintiff for damages, including, but not limited to, Decedent's pain and suffering for severe and permanent personal injuries sustained by Decedent, health and medical care costs, together with interest and costs as provided by law;

B. restitution and disgorgement of profits;

C. reasonable attorneys' fees;

D. the costs of these proceedings;

E. economic damages;

F. punitive damages; and

G. such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

Dated: September 26, 2022

Respectfully submitted,

/s/ Brian S. Katz

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CERTIFICATE OF SERVICE

I, Brian Katz, certify that on September 26, 2022, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service.

/s/ Brian S. Katz
Counsel for Plaintiff